

SCIENTIFIC

FOUNDATIONS

SERIES

Statutory Authority

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Statutory Authority

Recognizing that birth defects are a public health problem about which too little is known, the State Legislature in 1982 created the California Birth Defects Monitoring Program. From 1982-1990, seven pieces of legislation were passed and enacted mandating the Program to:

- Maintain an ongoing birth defects monitoring program statewide
- Track birth defects rates and trends
- Evaluate whether environmental hazards are associated with birth defects
- Investigate other possible birth defects causes
- Develop birth defects prevention strategies
- Conduct interview studies about causes
- Operate by contract with a qualified entity

The California Birth Defects Monitoring Program was subsequently modified in 2006 and 2007 to provide for

- The Program to become part of the Maternal, Child and Adolescent Program
- Provide a funding mechanism to support the pregnancy blood sample storage, testing and research activities of the Program
- Include within the Program umbilical cord blood samples received under the Hereditary Disorders Act

This document includes the Program's current statutory authority in the Health and Safety Code.

CHAPTER 1. BIRTH DEFECTS MONITORING PROGRAM

Section

- 103825. Legislative findings and declaration.
- 103830. Collection of information; system establishment; medical records.
- 103835. Scope of program; assessment of resources.
- 103840. Investigative studies.
- 103845. Advisory committee; membership.
- 103850. Confidentiality of information; research; review and approval; civil penalty.
- 103855. Contact for establishment and implementation of program.

Chapter 1 was added by Stats.1995, c.415 (S.B. 1360), § 4.

Historical and Statutory Notes Legislative findings relating to the nonsubstantive effect of Stats.1995, c. 415 (S.B. 1360), and the legislative intent not to create any new rights, see Historical and Statutory Notes under Health and Safety Code § 100100.

§ 103825. Legislative findings and declaration

The Legislature hereby finds and declares that birth defects, stillbirths, and miscarriages represent problems of public health importance about which too little is known; that these conditions lead to severe mental anguish on the part of parents and relatives and frequently to high medical care costs; and that a system to obtain more information about these conditions could result in development of preventive measures to decrease their incidence in the future. Therefore, it is the intent of the Legislature in enacting this section to accomplish all of the following:

- (a) To maintain an ongoing program of birth defects monitoring statewide. “Birth defect” as used in this chapter means any medical problem of organ structure
- (b) To provide information on the incidence, prevalence, and trends of birth defects, stillbirths, and miscarriages.
- (c) To provide information to determine whether environmental

hazards are associated with birth defects, still births, and miscarriages.

- (d) To provide information as to other possible causes of birth defects, stillbirths, and miscarriages.
- (e) To develop prevention strategies for reducing the incidence of birth defects, stillbirths, and miscarriages.
- (f) To conduct interview studies about the causes of birth defects.
- (g) To affirm the authority of the state department to contract with a qualified entity to operate the birth defects monitoring program statewide.

Historical and Statutory Notes

Derivation: Former § 10800, added by Stats.1982, c. 204, § 1, amended by Stats.1985, c. 1137, § 1; Stats.1989, c. 8, § 1; Stats.1990, c. 122, § 1.

§ 103830. Collection of information; system establishment; medical records

The director shall maintain a system for the collection of information, necessary to accomplish the purposes of this chapter. The director shall require health facilities, with 15 days’ notice, to make available to authorized program staff the medical records of children suspected or diagnosed as having birth defects, including the medical records of their mothers. In addition, health facilities shall make available the medical records of mothers suspected or diagnosed with stillbirths or miscarriages and other records of persons who may serve as controls for interview studies about the causes of birth defects. If it is necessary to photocopy records made available under this section, copying expenses shall be paid by the state department.

“Health facilities” as used in this section means general acute care hospitals, and physician-owned or operated clinics, as defined in Section 1200, that regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.

(Added by Stats 1995, c. 415 (S.B.1360), § 4.)

Historical and Statutory Notes

Derivation: Former § 10801, added by Stats.1982, c. 204, § 1, amended by Stats.1989, c. 8, § 2; Stats.1990, c. 122, § 3.

§ 103835. Scope of program; assessment of resources

The birth defects monitoring program shall operate statewide. It is the intent of the Legislature that the adequacy of program resources shall be assessed annually, and that the annual assessment shall include a consideration of at least all of the following factors:

- (a) The numbers of birth in the state.
- (b) The scope of program activities.
- (c) Any urgent situation requiring extraordinary commitment of present or planned program staff or resources.

(Added by Stats. 1995, c. 415 (S.B. 1360), § 4.)

Historical and Statutory Notes

Derivation: Former § 10802, added by Stats.1982, c. 204, § 1, amended by Stats. 1990, c. 122, § 4.

§ 103840. Investigative studies

The director shall use the information collected pursuant to Section 103830 and information available from other reporting systems and health providers to conduct studies to investigate the causes of birth defects, stillbirths, and miscarriages and to determine and evaluate measures designed to prevent their occurrence. The department's investigation of poor reproductive outcomes shall not be limited to geographic, temporal, or occupational associations, but may include investigation of past exposures.

(Added by Stats.1995, c. 415 (S.B.1360), § 4.)

Historical and Statutory Notes

Derivation: Former § 10803, added by Stats.1982, c. 204, § 1, amended by Stats.1990, c. 122, § 7.

§ 103845. Advisory committee; membership

The director shall appoint an advisory committee to advise on the implementation of this chapter. Each of the disciplines of epidemiology, hospital administration, biostatistics, maternal and child health and public health shall be represented on the committee. At least one of the members shall be a representative of the manufacturing industry.

(Added by Stats.1995, c. 415, (S.B.1360), § 4.)

Historical and Statutory Notes

Derivation: Former § 10804, added by Stats. 1982, c. 204, § 1, amended by Stats.1990, c. 122, § 8.

§ 103850. Confidentiality of information; research; review and approval; civil penalty

(a) All information collected pursuant to this chapter shall be confidential and shall be used solely for the purposes provided in this chapter. For purposes of this chapter, this information shall be referred to as "confidential information." Access to confidential information shall be limited to authorized program staff, and persons with a valid scientific interest, who meet qualifications as determined by the director, who are engaged in demographic, epidemiological or other similar studies related to health, and who agree, in writing, to maintain confidentiality.

(b) The department shall maintain an accurate record of all persons who are given access to confidential information. The record shall include: the name of the person authorizing access; name, title, address, and organizational affiliation of persons given access; dates of access; and the specific purpose for which information is to be used. The record of access shall be open to public inspection during normal operating hours of the state department.

(c) All research proposed to be conducted by persons other than program staff, using confidential information in the system, shall first be reviewed and approved by the director and the State Committee for the Protection of Human Subjects. Satisfaction of the terms of the director's rules for data access shall be deemed to establish a valid scientific interest for purposes of subdivision (a), entitling the researcher to review records collected pursuant to Section 103830 and to contact case subjects and controls. Before confidential information is disclosed pursuant to this section to any other person, agency, or organization, the requesting entity shall demonstrate to the department that the entity has established the procedures and ability to maintain the confidentiality of the information.

(d) Notwithstanding any other provision of law, any disclosure authorized by this section shall include only the information necessary for the stated purpose of the requested disclosure, and shall be made only upon written agreement that the information will be kept confidential, used for the approved purpose, and not be further disclosed.

(e) The furnishing of confidential information to the department or its authorized representative in accordance with this section shall not expose any person, agency, or entity furnishing the information to liability, and shall not be considered a waiver of any privilege or a violation of a confidential relationship.

(f) Whenever program staff, pursuing program objectives, deems it necessary to contact case subjects and controls, program staff shall submit a protocol describing the research to the director and to the State Committee for the Protection of Human Subjects. Once a protocol is approved by that committee, program staff shall be deemed to have established a bona fide research purpose, and shall be entitled to complete the approved project and contact case subjects and controls

without securing any additional approvals or waivers from any entity.

Derivation: Former § 10806, added by Stats.1985, c. 1147, § 2, amended by Stats.1989, c. 8, § 5; Stats.1990, c. 122, § 10.

(g) Notwithstanding any other provision of law, no part of the confidential information shall be available for subpoena, nor shall it be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding, nor shall this information be deemed admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason. Nothing in this section shall prohibit the publishing by the department of reports and statistical compilations relating to birth defects, stillbirth, or miscarriage that do not in any way identify individual cases or individual sources of information.

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(h) Any person who, in violation of a written agreement to maintain confidentiality, discloses any information provided pursuant to this section, or who uses information provided pursuant to this section may be denied further access to any confidential information maintained by the department. That person shall also be subject to a civil penalty of five hundred dollars (\$500). The penalty provided in this section shall not be construed as restricting any remedy, provisional or otherwise, provided by law for the benefit of the department or any person.

(i) Notwithstanding the restrictions in this section, an individual to whom the information pertains shall have access to his or her own information in accordance with Chapter 1 (commencing with Section 1798) of Title 1.8 of the Civil Code.

(Added by Stats.1995, c. 415, (S.B.1360), §4)

Historical and Statutory Notes

Derivation: Former § 10805, added by Stats.1982, c. 204, § 1, amended by Stats.1989, c. 8, § 4; Stats. 1990, c. 122, § 9.

§ 103855. Contract for establishment and implementation of program

The department may enter into a contract for the establishment and implementation of the birth defects monitoring program. The contract shall include provisions requiring full compliance with all the requirements of this chapter. The term of the contract may be in excess of one year, but no longer than three years. Funds shall be allocated in accordance with the state Budget Act. Funds withheld from the contractor at the conclusion of a fiscal year until specified tasks are completed shall be released promptly on proof of substantial completion, and shall not be offset against any funding for the subsequent fiscal year.

(Added by Stats.1995, c. 415, (S.B. 1360), § 4.)

Historical and Statutory Notes

§ 125002. Birth Defects Monitoring Program to become part of Maternal, Child, and Adolescent Program; prenatal blood samples; legislative intent; criteria to release samples for research, privacy and confidentiality

(a) In order to align closely related programs and in order to facilitate research into the causes of, and treatment for, birth defects, the Birth Defects Monitoring Program provided for pursuant to Chapter 1 (commencing with Section 103825) of Part 2 of Division 102 shall become part of the Maternal, Child, and Adolescent Health program provided for in Article 1 (commencing with Section 123225) of Chapter 1 of Part 2 of Division 106.

(Added by Stats.2006, c. 484, (S.B. 1555), § 4)

Historical and Statutory Notes

2007 Electronic Update, 2006 Legislation. Sections 1 and 6 of Stats.2006, c. 484 (S.B. 1555), provide:

“SECTION 1. This act shall be known and may be cited as the Maternal and Child Health Advancement Act.”

“SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime within the meaning of Section 6 of Article XIII B of the California Constitution”

§ 124977. Fees; legislative intent; creation of Birth Defects Monitoring Program Fund

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(b)(1) The department shall charge a fee to all payers for any tests of activities performed pursuant to this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter. Notwithstanding any other provision of law, any fees charged for prenatal screening and followup services provided to persons enrolled in the Medi-Cal program, health care service plan enrollees, or persons covered by health insurance policies, shall be paid in full and deposited in the Genetic Disease Testing Fund or the Birth Defects Monitoring Fund consistent with this section, subject to all terms and conditions of each enrollee's or insured's health care service plan or insurance coverage, whichever is applicable,

including, but not limited to, copayments and deductibles applicable to these services, and only if these copayments, deductibles, or limitations are disclosed to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

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(4) The department shall charge a fee for prenatal screening to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program.

(5) The initial prenatal screening fee increase for activities of the Birth Defects Monitoring Program shall be ten dollars (\$10).

(6) The only funds from the Genetic Disease Testing Fund that may be used for the purpose of supporting the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program are those prenatal screening fees assessed and collected prior to the creation of the Birth Defects Monitoring Program Fund specifically to support those Birth Defects Monitoring Program activities.

(7) The Birth Defects Monitoring Program Fund is hereby created as a special fund in the State Treasury. Fee revenues collected pursuant to paragraph (4) shall be deposited into the fund and shall be available upon appropriation by the Legislature to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program. Notwithstanding Section 16305.7 of the Government Code, interest earned on funds in the Birth Defects Monitoring Program Fund shall be deposited as revenue into the fund to support the Birth Defects Monitoring Program.

(Added by Stats.2006, c. 484, (S.B. 1555), § 3)

Historical and Statutory Notes

2007 Electronic Update, 2006 Legislation. INSERT

For urgency effective and other uncodified provisions relating to Stats.2006, c. 74 (A.B.1807), see Historical and Statutory Notes under Business and Professions Code § 1300.

Short title of act and reimbursement provisions relating to Stats. 2006, c. 484 (S.B.1555), see Historical and Statutory Notes under Health and Safety Code § 1604.6.

Section affected by two or more acts at the same session of the legislature, see Government Code § 9605.

2007 Legislation

Appropriation, cost reimbursement, urgency effective, and other uncodified provisions relating to Stats.2007, c. 188 (A.B.203), see Historical and Statutory Notes under Government Code § 13343.

2006 Main Volume

Legislative findings and declarations, and appropriations relating to Stats.2002, c. 1161 (A.B.442), see Historical and Statutory Notes under Business and Professions Code § 4426.

For Governor's signing message regarding Stats.2002, c. 1161 (A.B.442), see Historical and Statutory Notes under Health and Safety Code § 1356.

For legislative findings, declarations, and intent, cost reimbursement provisions, and urgency effective provisions relating to Stats.2004, c. 228 (S.B.1103), see Historical and Statutory Notes under Corporations Code § 17002.

Section 6.1 of Stats.2004, c. 228 (S.B.1103), provides:

"SEC. 6.1. The Legislature finds and declares all of the following:

"(a) Birth defects are the leading cause of infant death in California and the United States.

"(b) In California, more than 530,000 babies are born each year. According to the California Birth Defects Monitoring Program, one in 33 will be born with a debilitating condition. Of these, one in 11 will die.

"(c) Each year, newborn screen programs in all states test four million newborns to identify those who may have specific genetic and metabolic disorders that could threaten their life or long-term health and development. An estimated one in 3,000 newborn children carries a metabolic disorder that interferes with the growing child's development. California conducts newborn screening for the following disorders: phenylketonuria, galactosemia, sickle cell disease, and congenital hypothyroidism. Since 1980, more than 5,500 cases of these disorders have been detected from a small blood sample collected from each newborn shortly after birth. Without early detection and dietary treatment, children affected with these genetic conditions may suffer serious illness, severe physical or developmental disability, and death. The state's newborn screening program has proven effective in reducing the incidence of morbidity and mortality resulting from these four disorders.

"(d) Recent technological advances make it possible and affordable to screen for larger numbers of treatable metabolic disorders, more than 20 from a single sample. At least 26 states have implemented this new technology, tandem mass spectrometry. In order to keep pace with the rest of the nation, California needs to expand its newborn screening program.

"(e) In 2002-03, the Genetic Disease Branch (GDB) of the State Department of Health Services conducted a pilot project to expand newborn screening to 30 disorders.

"(f) According to the Centers for Disease Control and Prevention, the average lifetime cost of providing services to a person with moderate mental retardation is \$1,014,000. For every 20 additional cases identified through expanded screening, average lifetime cost savings could exceed \$20,000,000. Approximately 38 percent of infants born in California are eligible for Medi-Cal. Thus, significant costs are incurred by the state for providing medical care, special education, developmental services, and physical and speech, or occupational therapies to children with untreated

disorders. Health plans, insurance companies, and individual families also incur major costs.

"(g) Cost-benefit analyses have repeatedly found that expanded newborn screening produces significant net benefits. The GDB estimates that for every dollar spent on expanded screening, \$2.59 is saved in average lifetime costs. Moreover, expanded screening will save lives."

See Senate Daily Journal for the 2003-2004 Regular Session, page 5408, for additional information, including a letter dated August 26, 2004, from Senator Dede Alpert, regarding the intent of amendments to this section by Stats.2004, c. 228 (S.B.1103):

§ 124991. Storage and Use of Umbilical Cord Blood Samples; Fees; Confidentiality

(a) (1) The State Department of Public Health shall provide any umbilical cord blood samples it receives pursuant to Section 123371 to the Birth Defects Monitoring Program for storage and research. In administering this section the department shall ensure that the Birth Defects Monitoring Program meets at least one of the following conditions:

(A) The fees paid by researchers, investigators, and health care services providers pursuant to subdivision (c) shall be used to cover the cost of collecting and storing blood, including umbilical cord blood.

(B) The department receives confirmation that an investigator, researcher, or health care provider has requested umbilical cord blood samples for research or has requested cord blood samples to be included within a request for pregnancy and newborn blood samples through the program.

(C) The department receives federal grant moneys to pay for initial startup costs for the collection and storage of umbilical cord blood samples.

(2) The department may limit the number of units the program collects each year.

(b) (1) All information relating to umbilical cord blood samples collected and utilized by the Birth Defects Monitoring Program shall be confidential, and shall be used solely for the purposes of the program. Access to confidential information shall be limited to authorized persons who agree, in writing, to maintain the confidentiality of that information.

(2) The department shall maintain an accurate record of all persons who are given confidential information pursuant to this section, and any disclosure of confidential information shall be made only upon written agreement that the information will be kept confidential, used for its approved purpose, and not be further disclosed.

(3) Any person who, in violation of a written agreement to maintain confidentiality, discloses any information provided pursuant to this section, or who uses information provided pursuant to this section in a manner other than as approved pursuant to this section may be denied further access to any confidential information maintained by the department, and shall be subject to a civil penalty not exceeding one thousand dollars (\$1,000). The penalty provided in this section shall not be construed as to limit or otherwise restrict any remedy, provisional or otherwise, provided by law for the benefit of the department or any other person covered by this section.

(c) In order to implement this program, the department shall establish fees of an amount that shall not exceed the costs of administering the program, which the department shall collect from researchers and health care providers who have been approved by the department and who seek to use the following types of blood samples, collected by the Birth Defects Monitoring Program, for research:

provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner not approved in the research protocol, except as required by law or for authorized oversight of the research activity.

(Added by Stats. 2007, c. 517, (S.B. 962), § 3)

Historical and Statutory Notes – available upon codification of S.B. 962

(1) Umbilical cord blood.

(2) Pregnancy blood.

(3) Newborn blood.

(d) Fees collected pursuant to subdivision (c) shall be deposited into the Birth Defects Monitoring Program Fund created pursuant to paragraph (7) of subdivision (b) of Section 124977. Moneys deposited into the fund pursuant to this section may be used by the department, upon appropriation by the Legislature, for the purposes specified in subdivision (e).

(e) Moneys in the fund shall be used for the costs related to data management, including data linkage and entry, and umbilical cord blood storage, retrieval, processing, inventory, and shipping.

(f) The department shall adopt rules and regulations pursuant to existing requirements in the Birth Defects Monitoring Program, as set forth in Chapter 1 (commencing with Section 103825) of Part 2 of Division 102.

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(h) (1) For purposes of ensuring the security of a donor's personal information, before any umbilical cord blood samples are released pursuant to this section for research purposes, the State Committee for the Protection of Human Subjects (CPHS) shall determine if all of the following criteria have been met:

(A) The Birth Defects Monitoring Program contractors or other entities approved by the department have provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

(B) The Birth Defects Monitoring Program contractors or other entities approved by the department have provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research activity, unless the program contractors or other entities approved by the department have demonstrated an ongoing need for the personal information for the research activity and have provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The Birth Defects Monitoring Program contractors or other entities approved by the department have